AMENDMENT TO H.R. 4889

OFFERED BY MRS. JOHNSON OF CONNECTICUT

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Patient Safety Improvement Act of 2002''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. PATIENT SAFETY IMPROVEMENTS.

(a) IN GENERAL.—Title XI of the Social Security Act is amended by adding at the end the following new part:

''PART D—PATIENT SAFETY IMPROVEMENTS

''VOLUNTARY REPORTING OF PATIENT SAFETY DATA; DEFINITIONS

''SEC. 1181. (a) COLLECTION AND VOLUNTARY REPORTING OF PATIENT SAFETY DATA.—In order to improve patient safety and the quality of health care delivery, a health care provider (as defined in subsection (d)) may voluntarily collect and develop patient safety data (as defined in subsection (e)) and report such data to one or more patient safety organizations (as defined in subsection (f)) in a manner that is confidential and privileged (as described in section 1182).

''(b) USE OF PATIENT SAFETY DATA BY PATIENT SAFETY ORGANIZATIONS.—Patient safety organizations shall analyze the patient safety data reported and develop (and report

back to health care providers) information to improve patient safety and the quality of health care delivery and shall submit non-identifiable information derived from such data in a uniform manner to the Center for Quality Improvement and Patient Safety (for inclusion in the Patient Safety Database, if applicable). Such non-identifiable information may be disclosed and shared with other patient safety organizations. Identifiable patient safety data may be disclosed to other patient safety organizations with the explicit authorization of the reporting provider involved.

''(c) FUNCTIONS OF CENTER.—The Center for Quality Improvement and Patient Safety conducts patient safety activities consistent with section 1183.

''(d) HEALTH CARE PROVIDERS COVERED.—For purposes of this part, the term 'health care provider' means—

''(1) a provider of services (as defined in section 1861(u) and including a hospital, skilled nursing facility, home health agency, and hospice program) that provides services for which payment may be made under part A of title XVIII and the provider's employees;

''(2) a health care entity or individual that furnishes medical or other health services (as defined in section 1861(s)), other services described in section 1832(a)(2), or other items and services for which payment may be made under such title, including a physician (as defined in section 1861(r)); and

''(3) an organization offering a plan under part C of title XVIII.

''(e) PATIENT SAFETY DATA COVERED.—

''(1) IN GENERAL.—For purposes of this part, the term 'patient safety data' means any data, reports, records, memoranda, analyses, deliberative work, statements, or root cause analyses that are collected or developed to improve patient safety or health care quality and that—

''(A) are collected or developed by a health care provider for the purpose of reporting to a patient safety

organization and that are reported on a timely basis to such an organization;

''(B) are collected or developed by a patient safety organization or by the Center for Quality Improvement and Patient Safety, regardless of whether the data are transmitted to the health care provider that reported the original data; or

''(C) describes corrective actions taken by a health care provider in response to the provider's reporting of data to that organization, regardless of whether the organization has transmitted under subsection (f)(2) information to the health care provider that reported the original data.

''(2) CONSTRUCTION REGARDING USE OF DATA.—

''(A) INTERNAL USE PERMITTED TO IMPROVE PATIENT SAFETY, QUALITY, AND EFFICIENCY.—Nothing in this part shall be construed to limit or discourage a health care provider from developing and using patient safety data within the provider to improve patient safety, health care quality, or administrative efficiency of the provider.

''(B) TREATMENT.—Information that is collected or developed as patient safety data is not disqualified from being treated as patient safety data because of its development or use for the purposes described in subparagraph (A) and such development or use shall not constitute a waiver of any privilege or protection established under section 1182 or under State law.

''(f) QUALIFICATIONS OF PATIENT SAFETY ORGANIZATIONS.—

''(1) IN GENERAL.—For purposes of this part, the term 'patient safety organization' means a private or public organization that conducts activities to improve patient safety and the quality of health care delivery by assisting health care providers that report to such organizations and that has been certified by the Secretary as—

''(A) performing each of the activities described in paragraph (2); and

''(B) meets the other requirements of paragraphs (3) through (5).

''(2) ACTIVITIES DESCRIBED.—The activities referred to in paragraph (1)(A) are the following:

''(A) The collection and analysis of patient safety data that are voluntarily reported by more than one health care provider on a local, regional, State, or national basis.

''(B) The development and dissemination of information to health care providers and other patient safety organizations with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

''(C) The utilization of patient safety data to carry out activities under this paragraph to improve patient safety and to provide assistance to health care providers to minimize patient risk.

''(3) CONDUCT OF ACTIVITIES.—In conducting activities under paragraph (2), a patient safety organization shall—

''(A) maintain confidentiality with respect to individually identifiable health information;

''(B) submit non-identifiable information to the Center for Quality Improvement and Patient Safety in a format established by the Secretary; and

''(C) maintain appropriate security measures with respect to patient safety data.

''(4) ORGANIZATION REQUIREMENTS.—The requirements of this paragraph for an organization are that—

''(A) the organization is managed, controlled, and operated independently from health care providers which report patient safety data to it under this part;

''(B) if the organization no longer qualifies as a patient safety organization, with respect to any patient

safety data that it received from a health care provider, the organization shall do one of the following:

''(i) with the approval of the provider and another patient safety organization, transfer such data to such other organization;

''(ii) if practicable, return the data to the provider; or

''(iii) destroy the patient safety data;

''(C) if the organization charges a fee for the activities it performs with respect to health care providers, the fee shall be uniform among all classes or types of health care providers (taking into account the size of the health care provider);

''(D) the organization seeks to collect data from health care providers in a standardized manner that permits valid comparisons of similar cases among similar health care providers; and

''(E) the organization meets such other requirements as the Secretary may by regulation require.

''(5) LIMITATION ON USE OF PATIENT SAFETY DATA BY PATIENT SAFETY ORGANIZATIONS.—A patient safety organization may not use patient safety data reported by a health care provider in accordance with this part to take regulatory or enforcement actions it otherwise performs (or is responsible for performing) in relation to such provider.

''(6) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to patient safety organizations in providing recommendations and advice to health care providers reporting patient safety data under this part. Such assistance shall include advice with respect to methodology, communication, data collection, security, and confidentiality concerns.

''(g) CONSTRUCTION.—Nothing in this part shall be construed to limit or discourage the reporting of information relating to patient safety within a health care provider.

''CONFIDENTIALITY AND PEER REVIEW PROTECTIONS

''SEC. 1182. (a) IN GENERAL.—Notwithstanding any other provision of law, patient safety data shall be privileged and confidential in accordance with this section.

''(b) SCOPE OF PRIVILEGE.—Subject to the succeeding provisions of this section, such data shall not be—

''(1) subject to a civil or administrative subpoena;

''(2) subject to discovery in connection with a civil or administrative proceeding;

''(3) disclosed pursuant to section 552 of title 5, United States Code (commonly known as the Freedom of Information Act) or any other similar Federal or State law; or

''(4) admitted as evidence or otherwise disclosed in any civil or administrative proceeding.

''(c) CLARIFICATION OF SCOPE.—The privilege established by this section with respect to patient safety data described in section 1181(e)(1)(A) shall apply to information, such as records of a patient's medical diagnosis and treatment, other primary health care information, and other information, to the extent that such information was collected or developed for the purpose specified in such section and is reported in accordance with such section. Such privilege shall not apply to information merely by reason of its inclusion, or the fact of its submission, in a report under such section.

''(d) INFORMATION NOT SUBJECT TO PRIVILEGE.—The privilege established by this section shall not apply to one or more of the following:

''(1) MEDICAL RECORDS AND OTHER PRIMARY HEALTH RECORDS.—Records of a patient's medical diagnosis and treatment and other primary health records of a health care provider. Such privilege shall not apply to such information by reason of its inclusion within patient safety data.

''(2) FDA.—Relevant information disclosed by a health care provider or patient safety organization to the Food and Drug Administration, or to a person that is sub-

ject to the jurisdiction of such Administration, with respect to an Administration-regulated product or activity for which that entity has responsibility, for the purposes of activities related to quality, safety, or effectiveness of such Administration-regulated product or activity, subject to section 520(c) of the Federal Food, Drug, and Cosmetic Act.

''(3) NON-IDENTIFIABLE INFORMATION USED BY DATABASE.—Non-identifiable information from a patient safety organization to the Patient Safety Database and the further disclosure of such data by the Center for Quality Improvement and Patient Safety.

''(e) CONSTRUCTION RELATING TO STATE MANDATORY REPORTING REQUIREMENTS.—Nothing in this part shall be construed as preempting or otherwise affecting any State law mandatory reporting requirement for health care providers.

''(f) REPORTER PROTECTION.—

''(1) IN GENERAL.—A health care provider may not use against an individual in an adverse employment action described in paragraph (2) the fact that the individual reported, in good faith to the provider with the intention of having it reported to a patient safety organization or to a patient safety organization, information that would constitute patient safety data under section 1181(e)(1)(A) if the provider were to have submitted it on a timely basis to a patient safety organization in accordance with such section.

''(2) ADVERSE EMPLOYMENT ACTION.—For purposes of this subsection, an 'adverse employment action' includes—

''(A) the failure to promote an individual or provide any other employment-related benefit for which the individual would otherwise be eligible;

''(B) an evaluation or decision made in relation to accreditation, certification, credentialing or licensing of the individual; and

''(C) a personnel action that is adverse to the individual concerned.

''(g) PENALTY.—It is unlawful for any person to disclose any patient safety data in violation of the provisions of this section. Any person violating such provisions shall subject to the same sanctions under section 1160(c) (relating to, upon conviction, a fine of not more than $1,000, imprisonment for not more than 6 months, or both, per disclosure and payment of the costs of prosecution) as a person who discloses any information described in section 1160(a).

''(h) NO LIMITATION OF OTHER PRIVILEGES.—Nothing in this section shall be construed to limit other privileges that are available under Federal or State laws that provide greater peer review or confidentiality protections than the peer review and confidentiality protections provided for in this section.

''(i) APPLICATION OF PRIVACY REGULATIONS.—For purposes of applying the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191; 110 Stat. 2033)—

''(1) patient safety organizations shall be treated as business associates;

''(2) activities of such organizations described in section 1181(f)(2)(A) in relation to a health care provider are deemed to be health care operations of the provider; and

''(3) the disclosure of identifiable information by such an organization shall be treated as necessary for the proper management and administration of the organization.

Nothing in this section shall be construed to alter or affect the implementation of such regulation or such section 264(c).

''(j) NO WAIVER.—Disclosure of patient safety data under subsection (d)(2) shall not constitute a waiver of any privilege or protection established under this section or under State law.

''(k) CONTINUATION OF PRIVILEGE.—Patient safety data of an organization that is certified as a patient safety organization shall continue to be privileged and confidential, in accordance with this section, if the organization's certification is terminated or revoked or if the organization otherwise ceases to qualify as a patient safety organization until the data are otherwise disposed of in accordance with section 1181(f)(4).

''(l) SURVEY AND REPORT.—

''(1) SURVEY.—The Comptroller General of the United States shall conduct a survey of State laws that relate to patient safety data peer review systems, including laws that establish an evidentiary privilege applicable to data developed in such systems, and shall review the manner in which such laws have been interpreted by the courts and the effectiveness of such laws in promoting patient safety.

''(2) REPORT.—Not later than 9 months after the date of enactment of this section, the Comptroller General shall prepare and submit to Congress a report concerning the results of the survey conducted under paragraph (1).

''CENTER FOR QUALITY IMPROVEMENT AND PATIENT SAFETY

''SEC. 1183. (a) ESTABLISHMENT.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall establish a center to be known as the Center for Quality Improvement and Patient Safety (in this section referred to as the 'Center') in order to improve patient safety for items and services furnished through health care providers.

''(b) DUTIES.—

''(1) IN GENERAL.—The Secretary, through the Center, shall—

''(A) provide for the certification and recertification of patient safety organizations in accordance subsection (d);

''(B) collect and disseminate information related to patient safety;

''(C) establish a Patient Safety Database to collect, support, and coordinate the analysis of non-identifiable information submitted to the Database in accordance with subsection (e);

''(D) facilitate the development of consensus among health care providers, patients, and other interested parties concerning patient safety and recommendations to improve patient safety; and

''(E) provide technical assistance to States that have (or are developing) medical errors reporting systems, assist States in developing standardized methods for data collection, and collect data from State reporting systems for inclusion in the Patient Safety Database.

''(2) CONSULTATION.—In carrying out the duties under paragraph (1) (including the establishment of the Database), the Secretary shall consult with and develop partnerships, as appropriate, with health care organizations, health care providers, public and private sector entities, patient safety organizations, health care consumers, and other relevant experts to improve patient safety.

''(c) CERTIFICATION AND RECERTIFICATION PROCESS.—

''(1) IN GENERAL.—The initial certification and recertification of a patient safety organization under subsection (b)(1)(A) shall be made under a process that is approved by the Secretary and is consistent with criteria published by the Secretary.

''(2) REVOCATION.—Such a certification or recertification may be revoked by the Secretary upon a showing of cause (including the disclosure of data in violation of section 1182).

''(3) TERMINATION.—Such a certification provided for a patient safety organization shall terminate (subject to recertification) on the earlier of—

''(A) the date that is 3 years after the date on which such certification was provided; or

''(B) the date on which the Secretary revokes the certification.

''(d) IMPLEMENTATION AND CONSULTATION.—In carrying out subsection (c)(1), the Secretary shall—

''(1) facilitate the development of patient safety goals and track the progress made in meeting those goals; and

''(2) ensure that data submitted by a patient safety organization to the Patient Safety Database, as provided for under subsection (e), are comparable and useful for re-

search and analysis and that the research findings and patient safety alerts that result from such analyses are presented in clear and consistent formats that enhance the usefulness of such alerts.

''(e) PATIENT SAFETY DATABASE.—

''(1) IN GENERAL.—The Secretary, acting through the Center, shall—

''(A) establish a Patient Safety Database to collect non-identifiable information concerning patient safety that is reported on a voluntary basis; and

''(B) establish common formats for the voluntary reporting of data under subparagraph (A), including the establishment of necessary data elements, common and consistent definitions, and a standardized computer interface for the processing of such data.

''(2) DATABASE.—In carrying out this subsection, the Secretary—

''(A) shall establish and modify as necessary criteria to determine the organizations that may voluntarily contribute to, and the data that comprises, the Patient Safety Database;

''(B) shall ensure that the Patient Safety Database is only used by qualified entities or individuals as determined appropriate by the Secretary in accordance with criteria applied by the Secretary; and

''(C) may enter into contracts for the administration of the Database with private and public entities with experience in the administration of similar databases.

''(3) NON-IDENTIFIABLE INFORMATION.—For purposes of this part, the term 'non-identifiable information' means information that is presented in a form and manner that prevents the identification of any health care provider, patient, and the reporter of the information.

''(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out this section.

''INTEROPERABILITY STANDARDS FOR HEALTH CARE INFORMATION TECHNOLOGY SYSTEMS

''SEC. 1184. (a) IN GENERAL.—By not later than 2 years after the date of the enactment of this part, the Secretary shall develop or adopt (and shall periodically review and update) voluntary, national standards that promote the interoperability of health care information technology systems across all health care settings.

''(b) CONSULTATION AND COORDINATION.—The Secretary shall develop and update such standards in consultation with (and with coordination between)—

''(1) the National Committee for Vital and Health Statistics, and

''(2) the Medical Information Technology Advisory Board (established under section 3 of the Patient Safety Improvement Act of 2002).

''(c) DISSEMINATION.—The Secretary shall provide for the dissemination of the standards developed and updated under this section.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out this section.

''VOLUNTARY ADOPTION OF METHODS TO IMPROVE PATIENT SAFETY

''SEC. 1185. The Secretary shall encourage health care providers to adopt appropriate evidence-based methods to improve patient safety. Such methods shall not constitute national practice guidelines or conditions of participation under the medicare program under title XVIII.

''EVALUATION AND REPORT

''SEC. 1186. (a) EVALUATION.—The Comptroller General of the United States shall conduct a comprehensive evaluation of the implementation of this part. Such evaluation shall include an examination of the following:

''(1) The health care providers that reported patient safety data under this part and the patient safety organizations to which they reported the information.

''(2) What types of events were so reported on.

''(3) The usefulness of the analyses, information, and recommendations provided by patient safety organizations in response to such reported information.

''(4) The response of health care providers to such analyses, information, and recommendations.

''(5) The effectiveness of the program under this part in reducing medical errors.

''(b) REPORT.—Not later than 5 years after the date the provisions of this part are first implemented, the Comptroller General shall submit to Congress a report on the evaluation conducted under subsection (a).''.

SEC. 3. MEDICAL INFORMATION TECHNOLOGY ADVISORY BOARD.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 3 months after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall appoint an advisory board to be known as the ''Medical Information Technology Advisory Board'' (in this section referred to as the ''MITAB'').

(2) CHAIRMAN.—The Secretary shall designate one member as chairman. The chairman shall be an individual affiliated with an organization having expertise creating American National Standards Institute (ANSI) accepted standards in health care information technology and a member of the National Committee for Vital and Health Statistics.

(b) COMPOSITION.—

(1) IN GENERAL.—The MITAB shall consist of not more than 17 members that include—

(A) experts from the fields of medical information, information technology, medical continuous quality improvement, medical records security and privacy, individual and institutional health care clinical providers, health researchers, and health care purchasers;

(B) one or more staff experts from each of the following: the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, and the Institute of Medicine of the National Academy of Sciences;

(C) representatives of private organizations with expertise in medical infomatics;

(D) a representative of a teaching hospital; and

(E) one or more representatives of the health care information technology industry.

(2) TERMS OF APPOINTMENT.—The term of any appointment under paragraph (1) to the MITAB shall be for the life of the MITAB.

(3) MEETINGS.—The MITAB shall meet at the call of its chairman or a majority of its members.

(4) VACANCIES.—A vacancy on the MITAB shall be filled in the same manner in which the original appointment was made not later than 30 days after the MITAB is given notice of the vacancy and shall not affect the power of the remaining members to execute the duties of the MITAB.

(5) COMPENSATION.—Members of the MITAB shall receive no additional pay, allowances, or benefits by reason of their service on the MITAB.

(6) EXPENSES.—Each member of the MITAB shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

(c) DUTIES.—

(1) IN GENERAL.—The MITAB shall on an ongoing basis advise, and make recommendations to, the Secretary regarding medical information technology, including the following:

(A) The best current practices in medical information technology.

(B) Methods of implementing—

(i) health care information technology interoperability standardization; and

(ii) records security.

(C) A recommendation for a common lexicon for computer technology.

(D) Methods to promote information exchange among health care providers so that long-term compatibility among information systems is maximized, in order to one or more of the following:

(i) To maximize positive outcomes in clinical care—

(I) by providing decision support for diagnosis and care; and

(II) by assisting in the emergency treatment of a patient presenting at a facility where there is no medical record for the patient.

(ii) To contribute to (and be consistent with) the development of the patient assessment instrument provided for under section 545 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and to assist in minimizing the need for new and different records as patients move from provider to provider.

(iii) To reduce or eliminate the need for redundant records, paperwork, and the repetitive taking of patient histories and administering of tests.

(iv) To minimize medical errors, such as administration of contraindicated drugs.

(v) To provide a compatible information technology architecture that facilitates future quality and cost-saving needs and that avoids the financing and development of information technology systems that are not readily compatible.

(2) REPORTS.—

(A) INITIAL REPORT.—No later than 18 months after the date of the enactment of this Act, the MITAB shall submit to Congress and the Secretary an initial

report concerning the matters described in paragraph (1).

(B) SUBSEQUENT REPORTS.—During each of the 2 years after the year in which the report is submitted under subparagraph (A), the MITAB shall submit to Congress and the Secretary an annual report relating to additional recommendations, best practices, results of information technology improvements, analyses of private sector efforts to implement the interoperability standards established in section 1184 of the Social Security Act, and such other matters as may help ensure the most rapid dissemination of best practices in health care information technology.

(d) STAFF AND SUPPORT SERVICES.—

(1) EXECUTIVE DIRECTOR.—

(A) APPOINTMENT.—The Chairman shall appoint an executive director of the MITAB.

(B) COMPENSATION.—The executive director shall be paid the rate of basic pay for level V of the Executive Schedule.

(2) STAFF.—With the approval of the MITAB, the executive director may appoint such personnel as the executive director considers appropriate.

(3) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the MITAB shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

(4) EXPERTS AND CONSULTANTS.—With the approval of the MITAB, the executive director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

(e) POWERS.—

(1) HEARINGS AND OTHER ACTIVITIES.—For the purpose of carrying out its duties, the MITAB may hold such

hearings and undertake such other activities as the MITAB determines to be necessary to carry out its duties.

(2) DETAIL OF FEDERAL EMPLOYEES.—Upon the request of the MITAB, the head of any Federal agency is authorized to detail, without reimbursement, any of the personnel of such agency to the MITAB to assist the MITAB in carrying out its duties. Any such detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.

(3) TECHNICAL ASSISTANCE.—Upon the request of the MITAB, the head of a Federal agency shall provide such technical assistance to the MITAB as the MITAB determines to be necessary to carry out its duties.

(4) OBTAINING INFORMATION.—The MITAB may secure directly from any Federal agency information necessary to enable it to carry out its duties, if the information may be disclosed under section 552 of title 5, United States Code. Upon request of the Chairman of the MITAB, the head of such agency shall furnish such information to the MITAB.

(f) TERMINATION.—The MITAB shall terminate 30 days after the date of submission of its final report under subsection (c)(2)(B).

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary of Health and Human Services such sums as are necessary to carry out this section.